

HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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RFI Response: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

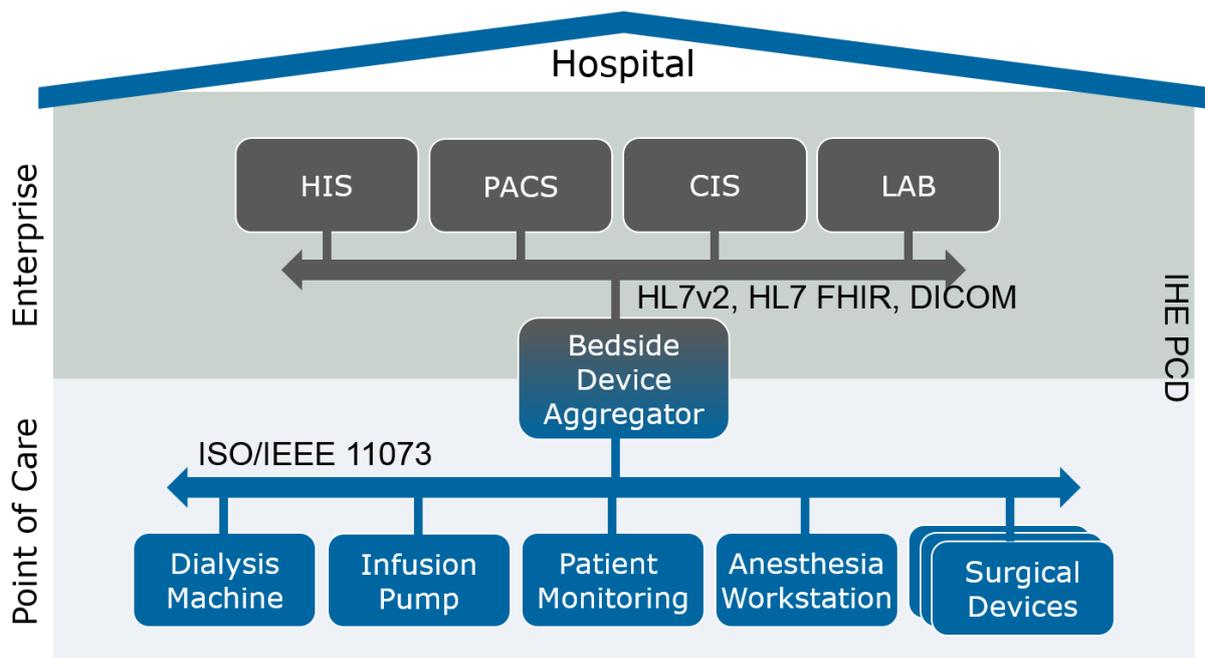
This is the response to the “Request for Information: Action on Interoperability of Medical Devices, Data, and Platforms To Enhance Patient Care”, posted on 15th of February 2019 from the German non-profit organization OR.NET e.V. in the version of the 14th of March 2019.

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1. What is your vision for addressing interoperability issues between medical devices, data, and platforms?

The challenges in interoperability between medical devices, data and platforms should be addressed by rigorous utilization of existing international standards and where needed profiles of these international standards.



From our point of view, there exists two layers of interoperability in a hospital environment:

- Enterprise Layer: Medical device data and information is exchanged and stored between enterprise level healthcare IT systems using standards from HL7 and DICOM that are profiled by means of IHE PCD profiles [1]. The medical device data is typically made available to the enterprise layer by a Point-of-Care Bedside Device Aggregator
- Point-of-Care Layer: Reliable data exchange between medical devices including Software as a Medical Device that also comprises external control with a focus on patient safety using standards from the family of IEEE 11073 especially IEEE 11073 SDC [2][3][4] for network-based data exchange. The Point-of-Care Bedside Device Device Aggregator participates also in the data exchange in order to provide the medical device data to the enterprise layer as well as provide data from the enterprise layer systems to the Point-of-Care Layer, e.g. Patient Demographics or Lab data.

In order to achieve a semantic and dynamic interoperable system across both layers it is of utmost importance that the semantics of the medical device data as implied by

the source is preserved. For this reason, the semantic model of both – the enterprise layer and the Point-of-Care Layer – have to be semantically the same even if the transmission medium and syntax is different. The above listed IHE PCD profiles and the IEEE 11073 SDC standards family ensure the utilization of the same nomenclature and a conceptual domain model for medical device data representation. The utilization of the IEEE 11073 nomenclature family and especially the subset of the harmonized portion of the nomenclature on both layers allow correct semantic interpretation of medical device data. IHE PCD also relies on the containment tree model representation of the IEEE 11073 standards family that is utilized also in the IEEE 11073 SDC standard series.

2. How would this plan to create interoperable systems address your key use cases and pain points?

The objective of the non-profit organization OR.NET e.V. is to foster the adoption of interoperability solutions based on international standards that address especially the problem of automatic dynamic networking of computer-controlled medical devices in the operating theater, intensive care units, emergency room or other acute care areas inside a hospital and the interaction of these devices with medically approved software.

The laid out plan would rely solely on international standards for both, the enterprise layer as well as the Point-of-Care layer. As only international standards are used the adoption of this interoperable system could be rolled out world-wide so that it is easy for a manufacturer to develop its products with the vision in mind. Moreover, it is beneficial for the users, e.g. responsible organizations, of such an interoperable system as the utilized technologies are mature.

3. Who are the relevant parties and their contributions to your interoperability solution?

- IEEE 11073 PoCD Working Group – IEEE Working group responsible for creating and maintaining the IEEE 11073 standards family for Point-of-Care Device including the nomenclature series as well as the IEEE 11073 SDC standards
- IHE PCD Working Group – IHE Patient Care Devices Working group responsible for profiling the medical device data representation for the enterprise layer utilizing standards like HL7v2 or HL7 FHIR.
- OR.NET e.V. – a German association with the objective to foster medical device interoperability and main contributor to the IEEE 11073 Standards Family as well as the SDC Conformance Principles and acting as a SDC Conformance Principles Governance Body.
- HIMSS - Ensuring that the IEEE SDC principles are implemented and enforced and together with OR.NET e.V. as well as IEEE 11073 PoCD WG responsible for managing and maintaining the related standard artefacts
- Manufacturers of Medical Devices
- Responsible Organizations, e.g. Hospitals

4. What are the challenges and impediments to making interoperability happen?
How might these issues be addressed and by whom?

Approximately ten years ago, our answer would have been that there are no interoperability standards available that could be used to implement the envisioned medical device, data, and platform interoperability. The lack of international interoperability standard was a major impediment to medical device manufacturers to provide medical devices to the market that can operate in a cross-vendor environment. For this reason, at that point in time there was typically a need that single system integrators ensures that the data is exported correctly from each individual device at the point of care and provided to the enterprise layer healthcare IT applications.

Today, with the current maturity of standards and profiles developed by IHE PCD community as well as the IEEE 11073 working group, our answer is that Medical Device Manufacturers should be asked to implement the available standards and the Responsible Organizations need to be willing to request for new medical devices the adheres to the above mentioned standards and profile. In the best case, the responsible organizations should also work with organizations like HIMSS or OR.NET to make sure that the conformance principles meet their needs.

5. Is the federal vision for a medical device, data, and platform interoperability end state outlined in this RFI viable?

When following the outlined two layer architecture approach and the described standards for creating an interoperable system as laid out above, we think that the federal vision for medical device, data and platform interoperability is viable. Demonstrators following the above outlined approach has been successful demonstrated over the last years that the medical device, data, and platform interoperability is achievable and it is expected that first IEEE 11073 SDC enabled devices are available in the market in 2019 [5].



The IEEE 11073 SDC standards family describes a basic architecture of an instance of a Service-Oriented Medical Device System (SOMDS) [2]. The instance of an SOMDS is called Service-Oriented Device Connectivity System (SDC System) and all participants follow the SDC Conformance principles.

An SDC Participant is a medical or non-medical device that is a physical devices or a software on its own or with an accessory, which implements the IEEE 11073 SDC Communication Protocol [2] with the SDC Participant Key Purposes either of the SDC Service Provider or SDC Service Consumer or both.

An SDC System provides System Functions by the combination of at least two SDC Participants communicating over the Medical IT-Network. Hence, an instance of System Function is therefore typically not realized by a Manufacturer, but by the Responsible Organization. However, a Responsible Organization cannot create arbitrary System Functions but only those supported by the System Function Contributions of the SDC Participants. SDC Conformant Devices only support System Functions that are safe and effective when SDC Conformant Devices are used together in a Medical IT-Network.

The IEEE 11073 SDC Communication Protocol is an Internet Protocol based service-oriented protocol supporting interoperability between SDC Participants.

An SDC System does not normally incorporate a central instance that controls the interoperation between SDC Participants. SDC Participants are able to discover each other within the same Medical IT-Network. SDC Participants themselves determine which other SDC Participants they will communicate with on the same network.

Due to the self-describing capabilities of the IEEE 11073 SDC Communication Protocol, the interoperability between SDC Participants is not limited to combinations predefined by a Manufacturer, but rather depends on the actual Services provided and required by the SDC Participants. Consequently, a new SDC Participant may provide new System Functions by leveraging the Services already provided by existing SDC Participants.

After the discovery, the SDC communication between two SDC Participant is cryptographically secured and monitored by the SDC Participant, such that failures of the Medical IT-Network or malicious attack is detected and will only lead to a detected interruption of the communication.

There are two types of data exchanges between SDC Participants:

- Data disclosing the state of an SDC Service Provider to at least one SDC Service Consumer
- Data generated by an SDC Service Consumer that is intended to control the state of an SDC Service Provider

The Service Consumer that intends to consume the data initiates the first type of data exchange. This type of data exchange is used e.g., for measurements, settings, or alerts. The SDC Service Provider providing the data describes the available data and the Services available to retrieve this data by means of the IEEE 11073 SDC Communication Protocol. The SDC Service Consumer requests the data directly or subscribes to reports that convey information about the state of the providing SDC Service Provider.

In the second type of data exchange, the SDC Service Provider that is intended to receive data for a control request describes the available operations by means of the IEEE 11073 30 SDC Communication Protocol. The SDC Service Consumer sending the control request data initiates this data exchange. This type of data exchange is used to externally control the settings of other devices, e.g. from an SDC Service Consumer physically located at a remote or at the same location of the SDC Service Provider.

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The IHE Patient Care Device Domain has developed several profiles for use cases mainly on the enterprise layer, e.g. Device Enterprise Communication or Alert Communication Management [1]. The implementation of the profiles relies on standards e.g. HL7 v2 or HL7 FHIR.

If the IHE PCD profiles are combined with the point-of-care device communication defined in the IEEE 11073 SDC series a full picture for medical device, data, and platform interoperability as outlined in the vision would be achieved.

6. References

- [1] IHE Patient Care Device (PCD) Technical Framework TF-1, https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol1.pdf
- [2] IEEE 11073-20701-2018, Service-Oriented Medical Device Exchange Architecture and Protocol Binding, <https://standards.ieee.org/standard/11073-20701-2018.html>
- [3] IEEE 11073-10702-2017, Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication, <https://standards.ieee.org/standard/11073-10207-2017.html>
- [4] IEEE 11073-20702-2016, Medical Devices Communication Profile for Web Services, <https://standards.ieee.org/standard/11073-20702-2016.html>
- [5] Press Release, Dräger Welcomes SDC New Interoperability Standard for Hospitals, https://www.draeger.com/Corporate/Content/04e_SDC_Launch_FIN.pdf

7. About the submitter of the comments

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The aim of the German non-profit organization OR.NET e.V. is to foster the adoption of interoperability solutions based on international standards that address especially the problem of automatic dynamic networking of computer-controlled medical devices in the operating theater, intensive care units, emergency room or other acute care areas inside a hospital and the interaction of these devices with medically approved software.

OR.NET e.V. was founded based on the results of the project OR.NET (2012-2016, funded by the German Government BMBF) that developed concepts for the secure dynamic networking of components in the operating room and clinic and started the international standardization process

OR.NET e.V. fosters the adoption of the developed concepts and standards by providing suitable training as well as service offerings with regards to verification and approval of medical device and IT solutions that are conformant with the developed international standards. Moreover, OR.NET e.V. actively supports the maintenance of the standards and develops additional interoperability specifications together with the Standards Development Organizations to ensure safe and secure dynamic networking of medical devices and IT systems.